

## **REMARKS/ARGUMENTS**

Reconsideration of this application is requested. Claims 14 and 58-66 are in the case.

### **I. ALLOWED CLAIMS**

It is noted, with appreciation, that claims 59, 60 and 64 are allowed.

### **II. THE FORMAL REJECTION**

Claim 40 is rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement because the recitation of "about  $10^{-6}$  M" in claim 40 allegedly is not supported by the claims and specification as originally filed. The Action notes that the specification asserts the peptide has a specific binding activity to CD23 of less than  $10^{-6}$  K<sub>d</sub> or between  $10^{-6}$  and  $10^{-11}$  M.

In response, new claim 65 (based on previous claim 40) has been amended to recite that the CD23-binding peptide has a specific binding activity to CD23 of K<sub>d</sub> less than  $10^{-6}$  M. New claim 66 claims the feature wherein the CD23-binding peptide has a specific binding activity to CD23 of K<sub>d</sub> comprised between  $10^{-6}$  and  $10^{-11}$  M. Support for new claims 65 and 66 appears in the originally-filed specification at, for example, page 13, lines 11-13. No new matter is entered.

In addition, as discussed in more detail below, independent claim 14 has been amended to recite that the CD23-binding peptide is dissolved in a pharmaceutically acceptable carrier solution. Support appears in the originally filed application at, for example, page 33, lines 5-6. No new matter is entered. All amendments presented

herewith are made without prejudice to the possibility of filing a continuing application directed to any subject matter disclosed in the present application.

### III. **THE ANTICIPATION REJECTION**

Claims 14 and 40 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by DE19749277 A1 (DE'277). The rejection is respectfully traversed.

As claimed, there is provided a pharmaceutical composition comprising at least one CD23-binding peptide consisting of the amino acid sequence Phe-His-Glu-Asn-Trp-Pro-Ser (SEQ ID NO:1) dissolved in a pharmaceutically acceptable carrier. The amendment to state that the peptide is "dissolved in a pharmaceutically acceptable carrier" is supported by the specification at page 33, lines 5-6.

DE'277 contains no disclosure (or suggestion) of the presently claimed composition. DE'277 relates to a use of the FHENWPS peptide as a chromatographic reagent for separation of albumin from biological fluids by affinity chromatography. In DE'277, the FHENWPS peptide is incubated with agarose in the presence of carbodiimide, and forms a stationary phase loaded on chromatography columns in order to bind albumin (DE'277, column 2, lines 24-33 and 54-66).

Thus, in DE'277, the FHENWPS peptide is immobilized on chromatography columns and attached to a carrier such as agarose. In contrast, in the presently claimed composition, the FHENWPS peptide is dissolved in a pharmaceutically acceptable carrier solution.

Moreover, in DE'277, FHENWPS peptide is never in solution of PBS. Rather, PBS is used in DE'277 as a neutral buffer for washing a chromatographic column, and

PBS flow through does not contain the FHENWPS. The FHENWPS peptide instead remains on the column. Withdrawal of the anticipation rejection of claim 14 is respectfully requested.

With regard to the anticipation rejection of claim 40, new claim 65 (based on previous claim 40) is dependent on claim 59 which is allowed. It is not understood therefore why claim 40 is rejected. In any event, new claim 65 recites a specific binding activity to CD23 of  $K_d = \text{less than } 10^{-6} \text{ M}$ . Claim 65 thus relates to CD23-binding peptides having sequences of SEQ ID NOS: 2-10, 31, 32, 34, 35, 40, 43 and 53-61 and having a specific binding activity to CD23 of  $K_d = \text{less than } 10^{-6} \text{ M}$ .

DE'277 contains no disclosure of such species. Withdrawal of the anticipation rejection of claim 40 over DE'277 is respectfully requested.

#### **IV. THE OBVIOUSNESS REJECTIONS**

Claims 14 and 61-63 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over DE'277 in view of USP 5,028,592 to Lipton. Claims 14 and 58 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over DE'277 in view of Heck *et al.*, Proc Natl Acad Sci 93 :4036-4039, April 1996 (Heck). The rejections are respectfully traversed.

As noted earlier, claim 14 provides a pharmaceutical composition comprising at least one CD23-binding peptide consisting of the amino acid sequence Phe-His-Glu-Asn-Trp-Pro-Ser (SEQ ID NO:1) dissolved in a pharmaceutically acceptable carrier. As of the filing date of the present case, one of ordinary skill in the art, aware of DE'277 would have been motivated to use the FHENWPS peptide as a chemical reagent for

separation of molecules by affinity chromatography. The skilled artisan would not have been motivated based on DE'277 to formulate the FHENWPS peptide as a pharmaceutical composition dissolved in a pharmaceutically acceptable carrier for use in the medical domain for treating certain disorders, such as rheumatoid arthritis.

The above-discussed deficiencies of DE'277 are not cured by Lipton or Heck, since neither of those disclosures describes nor suggests the FHENWPS peptide nor any pharmacological activity that might be associated with it. In light of this, the skilled artisan would not have been motivated to combine DE'277 and Lipton or DE'277 and Heck. Even if such combinations had been attempted (it is believed that would not have occurred), the presently claimed invention would not have resulted or have been rendered obvious thereby, because DE'277 provides no suggestion of a pharmaceutical composition comprising at least one CD23-binding peptide consisting of SEQ ID NO:1 dissolved in a pharmaceutically acceptable carrier. Withdrawal of the obviousness rejections and allowance of the application are, accordingly, respectfully requested.

Favorable action is awaited.

Respectfully submitted,

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